

### REMARKS

Claims 29-37, 50, and 52-62 are pending in the present application. Independent claim 50 is amended to recite a method of treating asthma to relieve asthmatic symptoms, the method comprising, providing a source of energy, and irradiating walls of an airway of an asthmatic lung with the source of energy at a wavelength and intensity which, over time, causes debulking of smooth muscle tissue of the asthmatic lung and prevents the lung tissue from replicating, wherein said irradiating step is performed by irradiating smooth muscle tissue in the asthmatic lung such that the ability of the smooth muscle to contract is reduced. Support for this amendment may be found in the application as filed, for example page 11, lines 5-9.

Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

#### Examiner Interviews

Applicant's attorney is thankful to the Examiner for the time and effort spent on the in-person interview conducted on October 19, 2007 as well as the telephone calls that occurred since the previous Office Action. The participants of this October 19, 2007 interview included Examiner Shay and Sanjay Bagade (applicant's counsel). During this interview, the parties discussed U.S. Patent No. 6,001,054 to Regulla et al., James et al. "The Mechanics of Airway Narrowing in Asthma", Am. Rev. Respir. Dis.; Vol. 139; 1989; pp 242-246, and U.S. Patent No. 5,053,033 to Clarke.

The parties reached an agreement that the amendment "smooth muscle" in line 2 of claim 50 would overcome the Regulla reference. The parties also agreed that the amendment "such that the ability of the smooth muscle to contract is reduced" at the end of the claim 50 would overcome the combination of James and Clarke tentative to an additional search.

Accordingly, in view of the amendments made to the independent claim, applicant believes that all outstanding issues are addressed and that sole independent claim 50 (and dependent claims 29-37 and 52-62) are in condition for allowance.

#### 35 USC §103(a) General Argument

Applicant notes that patent law clearly requires that the analysis supporting a rejection under 35 U.S.C. 103 must be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Applicant notes that these requirements are made clear in MPEP §2100. In addition, it is well established that when ascertaining the differences between the claimed invention and the cited references, the cited references must be considered as a whole. Applicant submits that by selectively choosing portions of a reference while disregarding other portions of that same reference, the Office Action relies upon impermissible hindsight reconstruction given the benefit of applicant's own invention.

§103 Rejection of claims 31, 33, 36, 50, and 52

The Office Action rejected claims 31, 33, 36, 50, and 52 under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,001,054 to Regulla et al. Applicant disagrees that the Office Action establishes a proper *prima facie* case of obviousness with respect to the claims prior to the current amendments.

First, applicant notes that the Office Action fails to provide any reasoning as to why one would modify the teachings of Regulla to arrive at the requirements of applicant's claims. Instead, the Office Action merely relies upon a conclusory statement. Again, established United States Patent Laws require the articulation of reasoning and rational to support a *prima facie* case of obviousness.

Next, Regulla teaches treating tumors by applying a metal surface adjacent to tissue so that radiation energy delivered to the metallic surface treats the adjacent tissue and that healthy tissue located a slight distance away is virtually unscathed by the radiation. See col. 8, lines 7-18. Regulla teaches such an approach as a therapeutic way to effectively treat localized tumors with lower doses of radiation so that non-diseased tissue is subjected to substantially less harmful effects. See also col. 2, lines 59-65. One skilled in the art would rely upon Regulla to teach targeted, site specific treatment of a tumor in a manner that would avoid damage to surrounding tissue, such as the smooth muscle tissue found beneath a wall of an airway.



Clearly, when taken in its entirety, Regulla teaches avoiding damage to tissue surrounding the site of a tumor. Applicant submits that one relying upon Regulla would not treat asthmatic lungs, much less airway smooth muscle, without the teachings of applicant's own disclosure.

However, due to the extended pendency of the present application and to expedite allowance of the subject application, applicant amends claim 50 to even further distinguish over Regulla in light of the Examiner Interview summarized above. Accordingly, applicant submits that this rejection by withdrawn.

§103 Rejection of claims 29, 32-34, 37, 50, and 56-59

The Office Action rejected claims 29, 32-34, 37, 50, and 56-59 under 35 U.S.C. §103(a) as allegedly being unpatentable over James et al. "The Mechanics of Airway Narrowing in Asthma", Am. Rev. Respir. Dis.; Vol. 139; 1989 in combination with U.S. Patent Nos. 5,053,033 to Clarke and 5,574,059 to Regunathan et al. Applicant disagrees that the Office Action establishes a proper *prima facie* case of obviousness with respect to the claims prior to the current amendments.

First, as noted in the title itself, James teaches the mechanics of airway narrowing in asthma. Secondly, James concludes on page 246, that the data "suggests that the treatment of asthma should focus on reversing the inflammatory changes in the airway wall an lumen as well as on the relaxation of the smooth muscle." Applicant is unable to find any teaching or suggestion in James of irradiating walls of an airway of an asthmatic lung with the source of energy at a wavelength and intensity which, over time, causes debulking of tissue of the asthmatic lung and prevents the lung tissue from replicating, wherein said irradiating step is performed by irradiating smooth muscle tissue in the asthmatic lung.

Next, Clarke addresses reducing proliferation, namely restenosis, of vascular tissue at an angioplasty site. Clarke teaches application of radiation to kill "smooth muscle cells at the site [of an angioplasty]" and expressly states that the application of energy is intended to reduce "the risk of restenosis, while minimizing damage to surrounding tissue." See col. 2, lines 47-50. Regunathan teaches inhibiting the proliferation of vascular smooth muscle with an I<sub>2</sub> imidazoline receptor agonist for those afflicted with atherosclerosis, restenosis, or traumatic injury to blood vessels. See col. 3, line 61 through col. 4, line 5.

Clearly, when taking these references together as a whole, applicant submits that one relying on James with Clarke and Regunathan would not treat asthmatic airways, much less airway smooth muscle with irradiation. Moreover, any suggested combination appears to be based on hindsight reconstruction rather than on the legal requirements of establishing a proper *prima facie* case of obviousness.

Again, due to the extended pendency of the present application and to expedite allowance of the subject application, applicant amends claim 50 to even further distinguish over James with Clarke in light of the Examiner Interview summarized above. Accordingly, applicant submits that this rejection by withdrawn.

§103 Rejection of claims 30 and 35

The Office Action rejected claims 30 and 35 under 35 U.S.C. §103(a) as allegedly being unpatentable over James in view of Clarke and Regunathan and in further combination with Vincent et al.

Applicant disagrees that the Office Action establishes a proper *prima facie* case of obviousness. The addition of Vincent does nothing to remedy the defects noted above. Accordingly, applicant requests withdrawal of this rejection.

§103 Rejection of claims 52-55

The Office Action rejected claims 52-55 under 35 U.S.C. §103(a) as allegedly being unpatentable over James in view of Clarke and Regunathan and in further combination with Lax et al.

Applicant disagrees that the Office Action establishes a proper *prima facie* case of obviousness. The addition of Lax does nothing to remedy the defects noted above. Accordingly, applicant requests withdrawal of this rejection.

Nonstatutory, Judicially Created Doctrine of Obvious-Type Double Patenting Rejections

Applicant disagrees with the double patenting rejections. In certain cases, the cited patents or patent applications are clearly patentably distinct subject matter. However, as noted herein, due to the extended pendency of the subject application and to expedite allowance, applicant submits the following terminal disclaimers:

Applicant also notes that under MPEP §804, if a provisional double patenting rejection is the only rejection remaining in an earlier filed application, then these rejections should be withdrawn in the earlier filed application.

Lastly, applicant notes that of the 33 double patenting rejections issued in the Office Action, four rejections are repeated verbatim for the following patent applications: 11/361,564; 11/608,606; 11/612,620; and 11/618,533.

Judicial Double Over U.S. Patent No. 7,027,869

A terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent No. 6,634,363

A terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent No. 6,411,852

A terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent No. 6,299,633



A terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent No. 6,283,989

A terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent No. 6,283,988

A terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent No. 6,200,333

A terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent No. 6,083,255

A terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent Application No. 11/614,919

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/612,620

Applicant notes that this rejection is repeated. Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/618,533

Applicant notes that this rejection is repeated. Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/609,242

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/608,606

Applicant notes that this rejection is repeated. Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/425,345

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/421,444

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/398,353

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/408,668

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/420,442

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/361,564

Applicant notes that this rejection is repeated. Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/117,905

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 10/810,276

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 10/809,991 now U.S. Patent Application No. 7,264,002

This application is now U.S. Patent Application No. 7,264,002 and a terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent Application No. 10/640,967 now U.S. Patent Application No. 7,273,055

This application is now U.S. Patent Application No. 7,273,055 and a terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent No. 6,273,907

A terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent No. 5,972,026

A terminal disclaimer is being submitted with this response.

Judicial Double Over U.S. Patent Application No. 11/617,512

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/562,910

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

Judicial Double Over U.S. Patent Application No. 11/614,914

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.



Judicial Double Over U.S. Patent Application No. 11/562,925

Per MPEP §804, applicant requests withdrawal of this rejection given that the present application is the first filed application.

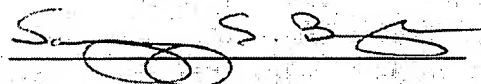
### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to Deposit Account No. 50-3973 referencing Attorney Docket No.

ASTXNA00100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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